

Patent claims

1. Process for the preparation of granules for a pharmaceutical formulation, wherein
 - (ii) a mixture comprising or consisting of
 - one or more active ingredients and
 - one or more retarding agentsis wetted with an oily substance and
 - (ii) the mixture is granulated.
2. Process for the preparation of granules for a pharmaceutical formulation, wherein
 - (i) one or more active ingredients are mixed with one or more retarding agents,
 - (ii) the mixture obtained is wetted with an oily substance and
 - (iii) the mixture obtained is granulated.
3. Process according to claim 1 or 2, wherein there is used a mixture according to claim 1 (i) or claim 2 (ii) comprising one or more excipients, especially comprising one or more fillers, flow-regulating agents, wetting agents and/or disintegrants.
4. Process according to any one of the preceding claims, wherein wetting with the oily substance is carried out by spraying.
5. Process according to any one of the preceding claims, wherein wetting with the oily substance is carried out at room temperature.
6. Process according to any one of the preceding claims, wherein there is provided for the mixture according to claim 1 (i) or according to claim 2 (ii) at least one corrosive and/or hydrophilic active ingredient.
7. Process according to any one of the preceding claims, wherein an active ingredient content of from 0.1 to 98 % by weight and especially from 0.5 to 70 % by weight is provided (based on the total weight of the granules).

8. Process according to any one of the preceding claims, wherein as retarding agent for the mixture according to claim 1 (i) or according to claim 2 (ii) there is provided a lipophilic retarding agent, especially in combination with a hydrogel matrix-forming agent and/or structural matrix-forming agent.
9. Process according to claim 8, wherein as retarding agent there is provided a combination of lipophilic retarding agent and hydrogel matrix-forming agent.
10. Process according to claim 8, wherein as retarding agent there is provided a combination of lipophilic retarding agent and structural matrix-forming agent with water-soluble excipient.
11. Process according to any one of the preceding claims, wherein as oily substance there is used a natural oil, a synthetic oil, a solution of wax in oil, or low-viscosity wax.
12. Process according to any one of the preceding claims, wherein a content of oily substance of from 0.2 to 20 % by weight and especially from 1 to 7.5 % by weight is provided (based on the total weight of the granules).
13. Process according to any one of the preceding claims, wherein the granules obtained are in addition provided with an outer phase of one or more retarding agents.
14. Process according to any one of the preceding claims, wherein granulation is carried out using a fluidised bed granulator or a plowshare mixer.
15. Process according to any one of the preceding claims, wherein granulation is carried out with the aid of a granule binder, especially in the form of a solution (granulating solution) of the granule binder in a solvent.
16. Process according to any one of the preceding claims, wherein the granules obtained are further processed to form tablets.
17. Process for the preparation of tablets, wherein granules that have been obtained according to any one of claims 1 to 15 are processed to form tablets.

18. Process according to claim 16 or 17, wherein for the further processing to form tablets or for the preparation of tablets, excipients are used, especially fillers, lubricants, flow-regulating agents and/or disintegrants.
19. Process according to claim 18, wherein the tablet is provided with a coating.
20. Granules obtained in accordance with a process according to any one of claims 1 to 15.
21. Granules for a pharmaceutical formulation, consisting of or comprising a mixture of
 - one or more active ingredients and
 - one or more retarding agents, wherein
 - the mixture has been wetted with an oily substance.
22. Granules according to claim 21, wherein the granules comprise at least one corrosive and/or hydrophilic active ingredient.
23. Tablet, obtainable in accordance with a process according to any one of claims 16, 17, 18 and/or 19.